December 8, 2001

Ms. Emily Clark
Product Specialist
Velsicol Chemical Corporation
10400 West Higgins Road
Suite 600
Rosemont, Illinois 60018

Dear Ms. Clark:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for dipropylene glycol dibenzoate, posted on the ChemRTK Web Site on July 13, 2001. I commend Velsicol for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

In general, Velsicol's Test Plan is adequate. However, as detailed in the attached comments, the Company needs to revise a number of robust summaries. The algal toxicity study robust summary is missing critical data elements to allow an adequate evaluation. The submitter needs to provide photodegradation, stability in water, and transportation/fugacity data for dipropylene glycol dibenzoate.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that the Company advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comments button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Dipropylene Glycol Dibenzoate

SUMMARY OF EPA COMMENTS

The sponsor, Velsicol Chemical Corporation, submitted a Test Plan and Robust Summaries to EPA dated June 1, 2001, for Dipropylene Glycol Dibenzoate (CAS No. 27138-31-4). EPA posted the submission on the ChemRTK HPV Challenge Web site on July 13, 2001.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. The submitter needs to provide photodegradation, stability in water, and transportation/fugacity data for dipropylene glycol dibenzoate (see comments below).

2. Health Endpoints. All appropriate SIDS level tests have been performed. The submitter needs to revise the developmental toxicity summary.

3. Ecological effects. EPA considers the aquatic acute toxicity studies for fish and daphnia adequate, with the exception of some data elements missing from the robust summaries. EPA reserves judgement on the adequacy of the algal study pending submission of missing data elements (see specific comments on robust summaries).

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE DIPROPYLENE GLYCOL DIBENZOATE CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

Adequate existing data are available for these endpoints.

Environmental Fate (Photodegradation, Stability in Water, Biodegradation, Fugacity).

The reported biodegradation data are adequate for the Challenge Program.

The submitter provided calculated photodegradation, stability in water, and transport (fugacity) data on diethylene glycol dibenzoate and triethylene glycol dibenzoate to satisfy the environmental fate end points, instead of collecting data on dipropylene glycol dibenzoate. EPA agrees with the submitter that these two chemicals contain the same functional groups -- aromatic rings, esters, and ether -- as dipropylene glycol dibenzoate. The submitter needs to explain why it decided to take this approach instead of providing data for dipropylene glycol dibenzoate. EPA prefers that the submitter provide measured data for photodegradation and stability in water where possible, and estimated data for transport and distribution (fugacity) for dipropylene glycol dibenzoate.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate existing data are available for these endpoints.

Ecotoxicity.

Adequate existing data are available for fish and daphnia. EPA considers the algal summary to be inadequate to allow an evaluation of the study. The submitter needs to supply measured toxicity values (see algal robust summary below).

SPECIFIC COMMENTS ON ROBUST SUMMARIES

Environmental Fate (Photodegradation, Stability in Water, Biodegradation, Fugacity)

EPA prefers using measured input values to calculate distribution (Fugacity Level III model) of dipropylene glycol dibenzoate in the environment.

Health Effects

Developmental Toxicity. The robust summary has identified a prenatal developmental NOAEL of 500 mg/kg/day (based on an increased incidence of cervical ribs in the 1000 mg/kg/day group) and a fetal growth and developmental NOAEL of 250 mg/kg/day (based on the increased incidence of incomplete ossification of the 5th and 6th sternebrae in the 500 and 1000 mg/kg/day groups). However, there is no basis for distinguishing between prenatal and fetal growth effects to justify two separate NOAELs. The summary should provide a single developmental NOAEL based on the most sensitive developmental effect–a NOAEL of 250 mg/kg/day and a LOAEL of 500 mg/kg/day based on developmental delay indicated by incomplete ossification of sternebrae. In addition, the summary should provide the incidence of incomplete ossification of the 5th and 6th sternebrae and its statistical significance.

Reproductive Toxicity. Estimated doses associated with the various dietary concentration levels need to be provided in the robust summary.

Environmental Effects and Ecotoxicity Studies

One robust summary each was submitted for fish, daphnia, and algal studies.

Fish. The following missing required data elements need to be submitted are: pH, DO, and total organic carbon (TOC).

Daphnia. The missing required data elements are water hardness and information on the toxic concentration for this endpoint. The 48-hour LC50 daphnia value is expressed as the percent of the loading concentration. However, EPA suggests calculating the mean measured value using the reported percent concentration of each sample tested.

Algae. The 96-hour EC50 value for the *Selenastrum capricornutum* test was inadequate for this endpoint because concentrations, though apparently measured, were not provided in the robust summary. In order to determine the toxicity for the algal end points (biomass and growth rate), all percent loadings of the tested samples and/or converted mean measured concentrations must be presented. Other required data elements missing are water hardness and pH.

Followup Activity

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.